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EXAMINER

LAMPRECHT, JOEL

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Objections

Claims 1-15, and 25-34 are objected to because of the following informalities:

Regarding claim 1, it is unclear where the preamble ends and the body of the claim begins based on the terms "having" and "comprising" on line one and the terms "the lumen" and "the catheter" lack antecedent basis. Regarding claim 2, it is unclear if the term "is" is inclusive or exclusive as the following term "formed into a coil shape" seems to be directed to a method of making the device rather than the device itself. Regarding claims 9 and 26, it is unclear what additional structural limitation has been set forth. Regarding claim 11, it appears the claim is directed to a method of making the device and is not meant to further limit the structure of the catheter. Regarding claims 15 and 34 the claims appear to be directed to the use of the device alone. Regarding claim 25, "the lumen of the sheath" lacks antecedent basis. Regarding claim 27, it is confusing to set forth an imaging device which includes an imaging device. Regarding claims 28 and 29, the use of the term "of" at the start of line two is confusing as it does not set forth if the material should comprise only of parylene or epoxy or if it should comprise of parylene or epoxy as a part of its composition. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27, 29-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 7081094

B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed patented invention of 7081094 discloses substantially the invention as currently claimed in the instant application including an imaging catheter, imaging device, traces over a sensor in the device, coaxial cabling, a magnetic core and conductive wire, tungsten/epoxy/silver/piezoelectric crystal at specific locations, driveshaft, capabilities for communication with a location system, parallel circuitry, and sonolucent media with accompanying insulation. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the sensor of the '094 patent as it is disposed to allow for electrical coupling via traces formed over a sensor as well as perform the additional features of the instant application.

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Claim 28 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 7081094 in view of Proudian et al (4,917,097). The '094 patent discloses all that is listed above but fails to mention the use of a parylene layer as a non-conductive material for surrounding a sensor. Attention is directed to the secondary reference by Proudian et al which discloses the use of parylene as a non-conductive transducer component for insulating and preventing shock to an electrical system (Col 8 Line 40-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized this parylene component rather than an epoxy as the two provide the same functionality and insulating capabilities.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-12, 27, 30, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohno et al (US 6,248,074 B1). Ohno et al disclose an imaging catheter comprising distal and proximal ends, an imaging device, a sensor for positioning location and tracking of the medical instrument located distally and coupled proximally via signal lines to the imaging device (Figure 3), and connective elements for coupling of the imaging device to a power supply. Tracing elements are incorporated for the coupling and powering of the catheter, and a driveshaft comprises imbedded signal

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lines (Figure 5, Col 5 Line 24-60). The magnetic sensor is used to communicate with a medical positioning system and the signal lines are comprised of a conductive material (ceramic, Col 6 Line 10-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8, 13-25, 26, 29, 31, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al ('074) in view of Hadjicostis et al (US 5,947,905). Ohno et al discloses all that is listed above and also discloses the use of a sonolucent media in the lumen of the sheath (Figure 1, Col 1 Line 20-45) but fails to disclose the use of a coaxial cable for running the system in parallel with the sensor, a piezoelectric

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crystal and acoustic lens for imaging (though an ultrasound imaging system is disclosed), or the use of a tungsten or epoxy material as the non-conductive backing material for the film layer. Attention is then directed to the secondary reference by Hadjicostis et al which teaches the use of a coaxial cabling for parallel system functionality and signal fidelity (Col 7 Line 35- Col 8 Line 30, Col 5 Line 25-40), a piezoelectric film (Col 2 Line 55 - Col 3 Line 25) layer for acoustic imaging with a non-conductive backing layer (C1m 7, Col 5 Line 55-Col 6 Line 24), and the use of tungsten or epoxy material as a non-conductive backing layer (C1m 31, 32, Col 6 Line 10-25). It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the film and connection components of Hadjicostis et al with the system of Ohno et al for the purpose of providing the best signal fidelity and clearest diagnostic image possible.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al ('074) in view of Proudian et al (US 4,917,097). Ohno et al discloses all that is listed above but fails to mention the use of parylene as a non-conductive material for use within the device. Attention is then directed to the secondary reference by Proudian et al which discloses the use of parylene as a non-conductive transducer component for insulating and preventing shock to an electrical system (Col 8 Line 40-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized this parylene component rather than an epoxy as the two provide the same functionality and insulating capabilities.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JML